

North Carolina Department of Health and Human Services Division of Public Health - Women's & Children's Health Section

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Beverly Eaves Perdue, Governor

Lanier M. Cansler, Secretary

February 3, 2010

TO:

2009 H1N1 Vaccine Providers

FROM:

Beth Rowe-West, R.N., B.S.N., Head

Immunization Branch

RE:

Shortened Shelf Life of Certain Lots of Sanofi Pasteur Monovalent 2009 (H1N1) Influenza Vaccine in Pre-

Filled Syringes

This memo is to inform you that some lots of Sanofi Pasteur's monovalent 2009 (H1N1) influenza vaccine in prefilled syringes will have a shorter expiration period than indicated on the label. The lots should be used by February 15, 2010, as indicated in the table below regardless of the expiration imprinted on the package. This is to ensure that the vaccine is used while it remains within its potency specification. There are no safety concerns with these lots of 2009 H1N1 vaccine. People who received vaccine from the lots listed below with shortened shelf life do not need to take any action.

These lots should be used by February 15, 2010, as indicated in the table below regardless of the expiration date imprinted on the package.

Influenza A (H1N1) 2009 Monovalent Vaccine in Pre-Filled Syringes Expiration Date Change

Product Code (NDC)	Description	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
49281-650-25	0.25mL syringes in 10-packs	UT014AA	March 4, 2011	February 15, 2010
		UT014BA	March 4, 2011	February 15, 2010
		UT014CA	March 4, 2011	February 15, 2010
		UT014DA	March 4, 2011	February 15, 2010
		UT014FA	March 27, 2011	February 15, 2010
		UT014EA	March 25, 2011	February 15, 2010
		UT029DA	April 7, 2011	February 15, 2010
		UT029BA	April 6, 2011	February 15, 2010
		UT029CA	April 6, 2011	February 15, 2010
		UT029EA	April 8, 2011	February 15, 2010
		UT030EA	April 10, 2011	February 15, 2010
		UT030FA	April 11, 2011	February 15, 2010
		UT033CA	April 12, 2011	February 15, 2010
		UT033DA	April 12, 2011	February 15, 2010

Product Code (NDC)	Description	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
49281-650-50	0.5mL	UP033CA	April 16, 2011	February 15, 2010
	syringes in	UP036CA	April 19, 2011	February 15, 2010
	10-packs	UP034BB	April 22, 2011	February 15, 2010
		UP036EA	May 3, 2011	February 15, 2010
		UP037CA	April 30, 2011	February 15, 2010
		UP037DA	May 2, 2011	February 15, 2010
		UP048CA	May 6, 2011	February 15, 2010
		UP040CA	May 4, 2011	February 15, 2010
		UP048DA	May 9, 2011	February 15, 2010
		UP049FA	May 16, 2011	February 15, 2010
		UP049CA	May 11, 2011	February 15, 2010
		UP049DA	May 13, 2011	February 15, 2010
		UP035BA	April 15, 2011	February 15, 2010
		UP059DA	May 16, 2011	February 15, 2010
		UP060CA	May 17, 2011	February 15, 2010
		UP060DA	May 19, 2011	February 15, 2010
		ŲT047BA	May 11, 2011	February 15, 2010
		UP033AB	April 9, 2011	February 15, 2010
		UP041BA	April 30, 2011	February 15, 2010
		UT041AA	April 29, 2011	February 15, 2010
		UT034AA	April 19, 2011	February 15, 2010
		UT045BA	May 5, 2011	February 15, 2010
		UP061DA	May 21, 2011	February 15, 2010
		UP061FA	May 23, 2011	February 15, 2010
		UP035AA	April 12, 2011	February 15, 2010
		UT048BA	May 12, 2011	February 15, 2010
		UT058BA	May 16, 2011	February 15, 2010
		UT059AA	May 18, 2011	February 15, 2010
		UT058AA	May 14, 2011	February 15, 2010
		UT061GA	May 24, 2011	February 15, 2010
		UP045EA	June 9, 2011	February 15, 2010
49281-650-90	0.5mL	UT036DA	April 26, 2011	February 15, 2010
	syringes in	UT040BA	April 28, 2011	February 15, 2010
	25-packs	UT047AA	May 9, 2011	February 15, 2010
		UT046BA	May 9, 2011	February 15, 2010
		UT046AA	May 4, 2011	February 15, 2010

All pre-filled syringes that have not been used by February 15, 2010 should be discarded in an appropriate manner, or you may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64th Street, Milwaukee, WI 53218. If you transferred vaccine to another provider in your community, please share this information with them. Also be sure to pass along Sanofi Pasteur's directions for returning unused vaccine.

The change in expiration date described here is specific to the 50 lots of Sanofi Pasteur 2009 H1N1 influenza vaccine in pre-filled syringes listed in this memo. However, a related recall (See http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00306) was conducted recently, which involved lots from

Sanofi Pasteur's 2009 H1N1 vaccine in 0.25 mL and 0.5 mL pre-filled syringes. These actions do not affect Sanofi Pasteur's 2009 H1N1 vaccine in multi-dose vials.

Sanofi Pasteur will send a notification to providers who received doses from any of the 50 lots of vaccine described above.

For More Information:

- CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, is available 24 hours a day, every day.
- For other inquiries, please contact Sanofi Pasteur Customer Services: 1-800-VACCINE (1-800-822-2463) or visit www.vaccineshoppe.com
- For a list of all the 2009 (H1N1) influenza vaccine impacted by recalls and expiration date changes, visit www.immunizenc.com/h1n1lots.htm

SMT cc: Regional Immunization Staff Central Office Staff